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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/01/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,241

Applicant(s)

MENEI ET AL

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 07/01/04. Previously submitted claims 1-27 are cancelled. New claims 28-40 are presented and pending.

Although, claim 30 contains polysorbate, the rejection of polysorbate under 35 USC second paragraph will not be made in light of applicants' previous argument, which is considered persuasive.

Claim Rejections - 35 USC § 103

1. The rejection of claims 2-7, 9-15, 17-20, 22, 25 and 27 under 35 U.S.C. 103(a) as being unpatentable over Emerich et al. ("Injectable Chemotherapeutic Microspheres and Glioma II: Emerich et al. ("Injectable Chemotherapeutic Microspheres and Glioma II: Enhance Survival Following Implantation Into Deep Inoperable Tumors," Pharmaceutical Research, Vol. 17, no. 7, 2000, pages 776-781) in view of Kubo et al. ("Treatment of malignant brain tumor with slowly releasing anticancer drug-polymer composites," International Journal of Radiation Applications and Instrumentation. Part C. Radiation Physics and Chemistry, Vo. 39, issue 6, June 1992, pp 521-525) is withdrawn in light of cancellation of said claims.

2. The rejection of claims 2-9, 16-18, 20 and 27 under 35 U.S.C. 103(a) as being unpatentable over Boisdstron-Celle et al. ("Preparation and Characterization of 5-Fluorouracil-loaded microparticles as Biodegradable Anticancer Drug Carriers," J. Pharm. Pharmacol. 1999, 47: 108-114) in view of Kubo et al. ("Treatment of malignant brain tumor with slowly releasing anticancer drug-polymer composites," International Journal of Radiation Applications and Instrumentation. Part C. Radiation Physics and Chemistry, Vo. 39, issue 6, June 1992, pp 521-525) is withdrawn in light of the cancellation of said claims.

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Response to Arguments

3. Applicants' arguments with respect to claims 2-7, 9-15, 17-20, 22, 25 and 27 and claims 2-9, 16-18, 20 and 27 rejected separately over the cited art of record have been considered but are moot in view of the new ground(s) of rejection.

The introduction of new claims 28-40 gives rise to the new rejection below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 28-36, 40 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Faisant et al. (US 2002/0051749).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

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Faisant discloses a sterile suspension containing 1 to 1.5% viscosity modifier, 0.5 to 1.5% surfactant, 3.5 to 4.5% isotonicity agent and biodegradable microspheres that contain anticancer agent (paragraph [0071]). The anticancer agent is 5-FU in amounts of between 50 and 200 mg; the isotonicity agent is mannitol; surfactant is polysorbate; viscosity modifier is carboxymethylcellulose; the sterile suspension is injected by stereotaxy into the tumor area; the treatment with the biodegradable microspheres containing the anticancer drug is followed with radiotherapy (paragraphs [0039]-[0050] and Faisant directs the disclosure to treating glioblastoma or malignant glial tumors (paragraph [0001]-[0005])). The examined claims are directed to treating inoperable tumors with composition that are the same as composition of Faisant and the Faisant reference meets the limitations of the claims.

US 2003/0175356 to Faisant et al. is equal relevance to the instant claims as US 2002/0051749 to Faisant et al. described immediately above.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 28-40 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of copending Application No. 10/451,216, now published as

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20040180095. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Although the co-pending claims recite the use of biodegradable microspheres for the treatment of inoperable tumors in humans by administering the biodegradable microspheres by stereotactic injection directly into the tumor, the co-pending claims are interpreted as method of treating human patients suffering from inoperable tumors by administering the biodegradable microspheres directly into the tumors by stereotactic injection (co-pending claim 1). The composition of the microspheres in the co-pending and the examined claims are the same. The types of brain tumors recited by both the co-pending and the examined claims are the same. The anticancer drug, 5-FU is recited by both sets of claims.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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